DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-13, 15, 20, 22, 23, 25-39, 41, 42, 44-54, 57, 58, 96 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biscup (6,245,108) alone; or, in the alternative, over Biscup in view of Boyd et al. (6,468,311).

Biscup discloses a spinal implant comprising a top, 20, a bottom, 30, a curved anterior side, 60, a curved posterior side, 70, (see column 4, lines 16-17 and column 10, lines 44-46) and an opening, 130, extending through the spinal implant from the top to the bottom, protrusions, 80, a recess, 150, groove, 140 (see figures 1 and 2). The proximal end can be substantially flat or rounded and the distal end can be tapered or curved (see figures 1 and 2 and column 5, lines 37-48).

The protrusions can differ in height, pattern, shape, spacing, coarseness and fineness (see column 4, lines 38-62). The implant can comprise bone, polyether ether ketone, metal, titanium, one or more openings for X-ray sensitive material, the top can be treated to promote osseointegration of the implant with bone, the top can be roughened to promote fusion of the spinal implant with bone, and the opening can

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receive packing material (see column 3, lines 56-67, column 4, lines 1-10, and 38-67, column 5, lines 1-36, and column 10, lines 32-37).

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With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Biscup, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Biscup teaches the claimed invention except for explicitly reciting that the implant can comprise two curved sides so as to be substantially kidney-shaped. However, it would have been obvious to have formed the second side wall 70 of Biscup to be non-planar, e.g., curved, in order to provide longer walls and hence to have more contact between the implant upper and lower wall surfaces and the surfaces of the vertebrae (see, e.g., Biscup, col. 9, lines 3-7 and 12-15). Determining a range of curvatures in such an instance, including wherein the sidewall curvatures 60 and 70 are substantially similar, would involve only routine skill in the art, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Alternatively, it would have been obvious to have provided the implant of Biscup with curved sides so as to be substantially kidney-shaped in view of Boyd et al. Biscup discloses that "the implant can be used with a modular component that can be attached and assembled between two implants to create a construct (ALIF type) cage." (see col. 11, lines 25-27). Boyd et al. disclose such an implant construct 10 comprising a modular component 28 assembled between two substantially kidney shaped implants 12 and 13 (see, e.g., Figs. 1, 2 and 3a, Abstract, col. 2, lines 15-32, col. 4, lines 35-42). This configuration provides a substantially rigid structure that inhibits movement of the lateral spacers and provides support near the outer wall of the vertebra, while still allowing for a minimally-invasive surgery. It would have been obvious to a person having ordinary skill in the art to have provide the implants of Biscup with a substantial kidney shape and a construct therebetween, in view of Boyd et al., in order to provide a substantially rigid structure that inhibits movement of the lateral spacers and to provide support near the outer wall of the vertebra, while still allowing for a minimally-invasive surgical procedure. It is noted that even absent the teachings of Biscup and Boyd et al. regarding the curved walls and kidney-shape, it would have been obvious to have formed the implant of Biscup with curved walls and a kidney shape as doing so is old and well-known in the art of spinal implants (as evidenced by, for example, the art which has been cited on the accompanying PTO-892, which is only a sampling of the numerous implants having such a configuration).

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biscup (6,245,108) alone; or, alternatively, over Biscup in view of Boyd et al.

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(6,468,311), as set forth above, and further in view of Ross et al. (US Patent Publication Number 2005/0004671).

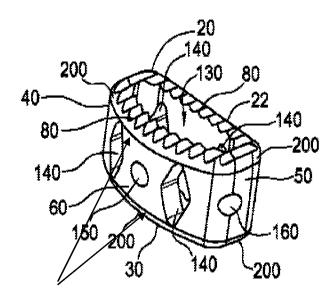
The device of Biscup, or alternatively, the device of the combination of Biscup and Boyd et al., discloses the claimed invention except an inner surface of the anterior side and an inner surface of the posterior side each comprising one or more projections extending into the opening. Ross et al. disclose a spinal implant and an inner surface of the anterior side and an inner surface of the posterior side each comprising one or more projections extending into the opening (see figure 5-7). In addition, Ross et al. teach the use of the projections as support structures (see paragraph 0048). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Biscup or the device of the combination of Biscup and Boyd et al., with an inner surface of the anterior side and an inner surface of the posterior side each comprising one or more projections extending into the opening, in view of Ross et al., in order for the projections to serve as support structures for the implant.

Response to Arguments

Applicant's arguments filed 30 June 2009, with respect to the claims as now amended, have been considered but remain unpersuasive. Examiner incorporates by reference previous responses to Applicants arguments. In addition, it is noted that the grooves extend from the top to the bottom surfaces--even as now claimed. The beginning of the top of the implant is shown with an arrow, as is the corresponding beginning of the bottom (see illustration below). Applicant should amend the claims to

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recite not only that the groove is located on each curvature and extends from the top to the bottom, etc., as claimed, but also, that the groove extends through the top and bottom of the implant, or the like. Again, by way of emphasis, as now claimed, the groove must only extend from the top to the bottom, i.e., begin at the top, etc. An amendment that would overcome the present grounds of rejection must additionally recite that the groove passes through the claimed top and bottom, or the like. The grooves in the prior art are at least substantially equidistant from the end.



top and bottom

<u>Illustration</u>

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/ Examiner, Art Unit 3733 /Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733